



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Sonoma Orthopedics Products, Incorporated  
% Ms. Dawn Norman  
Memphis Regulatory Consulting, LLC  
3416 Roxee Run Cove  
Bartlett, Tennessee 38133

June 12, 2015

Re: K150376

Trade/Device Name: Sonoma Cancellous Bone Screw and Washer  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC, HTN  
Dated: May 1, 2015  
Received: May 5, 2015

Dear Ms. Norman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

## Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement on last page.

510(k) Number (*if known*)

K150376

Device Name

Sonoma Cancellous Bone Screws and Washers

### Indications for Use (*Describe*)

The Sonoma Cancellous Screws are intended for use in the fixation of bone fractures appropriate for the size of the screw. The washer is used to increase bone contact area and prevent the screw head from subsiding into the bone. These screws are not intended for attachment or fixation to the posterior elements (pedicles) of cervical, thoracic, or lumbar spine.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

**510(k) Summary**  
*Sonoma Cancellous Bone Screw and Washer*  
*February 12, 2015*

**Company:** Sonoma Orthopedics Products, Inc  
1388 Busch Parkway  
Buffalo Grove, IL 60089  
Phone: 707-526-1335  
Fax: 707-526-2022

**Establishment**  
**Registration:** 3007038372

**Primary Contact:** Dawn Norman, MS  
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**Company/Secondary Contact:**

**Kyle Lappin**  
Sonoma Orthopedics Products, Inc  
1388 Busch Parkway  
Buffalo Grove, IL 60089  
Phone: 707-526-1335  
Fax: 707-526-2022

**Trade Name:** Sonoma Cancellous Bone Screw and Washer

**Common Name:** Single/multiple component metallic bone fixation appliances and accessories  
Smooth or threaded metallic bone fixation fastener

**Classification:** Class II

**Regulation Number:** 21 CFR 888.3030; 21 CFR 888.3040

**Panel:** 87- Orthopedic

**Product Code(s):** HWC, HTN

**Predicate Device(s):** K983495 Syntec Bone Screws

**Device Description:** Sonoma Cancellous Bone Screws and Washers are a family of stainless steel screws and washers used for various skeletal repairs where cancellous screw thread profiles are clinically desired. The screws are offered in range of diameters from 4mm to 7.3mm, in both cannulated and solid configurations. The screw dimensions including thread profile, thread length, core diameter, cannulation diameter (where applicable), head diameter, overall length, and driving socket size are equivalent to the predicate device. Where applicable, these features are dimensioned as described by ASTM F543-13 (i.e. 4.0mm and 6.5mm solid screws). The washers are sized according to screw diameter and can be used to prevent head subsidence in soft bone. The screws and washers are manufactured from 316 stainless steel per ASTM F138.

**Indications for Use:** The Sonoma Cancellous Screws are intended for use in the fixation of bone fractures appropriate for the size of the screw. The washer is used to increase bone contact area and prevent the screw head from subsiding into the bone. These screws are not intended for attachment or fixation to the posterior elements (pedicles) of cervical, thoracic, or lumbar spine.

**Substantial Equivalence:** The intended uses of the subject device are the same as the predicate device. The materials of construction of the subject device are the same as the predicate device. The dimensions of the subject device are equivalent to the dimensions of the predicate device. The indications for use of both the subject and predicate devices are for the fixation of fractured bones. Thus, the subject device is substantially equivalent to the predicate device.

**Performance Testing:** Engineering analysis and mechanical testing according to ASTM F543-13 in torsional properties and axial pullout testing demonstrate the subject device is substantially equivalent to the predicate device.